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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/989,055   | 11/21/2001  | Jaime Vargas         | 032405-065          | 1153             |
| 33109  | 7590        | 07/19/2004           | EXAMINER            |                  |
| CARDICA, INC.<br>900 SAGINAW DRIVE<br>REDWOOD CITY, CA 94063 |             |                      | WOO, JULIAN W       |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3731                |                  |

DATE MAILED: 07/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/989,055

Applicant(s)

VARGAS ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 34-46, 50-59, 61, and 62 is/are pending in the application.
- 4a) Of the above claim(s) 35-42 and 55-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34, 43-46, 50, 58, 59, 61 and 62 is/are rejected.
- 7) ☒ Claim(s) 51-54 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election without traverse of 34, 43-54, and 58-60 in the reply filed on April 21, 2004 is acknowledged. Claims 35-42 and 55-57 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Weldon et al. (5,221,259). Weldon et al. disclose, in the figures, a device with a deformable anastomosis device (34) with a deployed state (see fig. 7 at A), a deployment tool (20) and a sheath (10) having a cutting element (14) at its distal end.

4. Claim 43-46 and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by LeMole (5,893,369). LeMole discloses, in figure 8, a device for piercing the wall of a target vessel, where the device has a tubular sheath (30) with a circumferential distal edge, a retractable cutting element (32) slidable within the sheath, and a cable (38)

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connected to the cutting element; where the cutting element has two pieces or a tapered tip (34) and an anvil surface (32), and a shaft (36) extending from the anvil surface, where a storage position (proximal of the cutting element) is defined relative to the sheath.

5. Claims 58, 59, 61, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Milo (5,403,338). Milo discloses, in figures 1-3, a device with a deployment tool (2) and a sheath (1) having a cutting element (7 or 9) at its distal end. With respect to claims 43-48, 50, and 58-60, Milo discloses a device for piercing the wall of a target vessel, where the device has a tubular sheath (1) with a sharpened distal end (9), a lumen, and a cutting element (7) slidable within the sheath, where the cutting element has a tapered tip (at 5), and where the cutting element is configured to trap, retain and remove a tissue ring.

***Allowable Subject Matter***

6. Claims 51-54 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a device for piercing the wall of a target vessel, where the device has, inter alia, a tubular sheath, a cutting element, and a cable attached to the cutting element, where the cutting element has a pin extending therefrom, the sheath has a slot, and the pin is movable within the slot.

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As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

***Response to Amendment***

8. Applicant's arguments with respect to claim 34 has been considered but are moot in view of the new ground(s) of rejection. With respect to the rejection of claims 43, the amendment has overcome the rejection based on Williamson, IV. With respect to rejections based on LeMole and Milo: See the rejections above.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is 703-308-0421. The examiner can normally be reached on M-F, 6:30-4:00, Alt. Fridays Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on 703-308-2496. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo  
Primary Examiner  
Art Unit 3731